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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/106,839 09/27/99 BRIGHT

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EXAMINER

HN12/1002

PILLSBURY MADISON & SUTRO LLP
INTELLECTUAL PROPERTY GROUP
1100 NEW YORK AVENUE NW
9TH FLOOR EAST TOWER
WASHINGTON DC 20005-3918

NGUYEN, L

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/405,839

Applicant(s)

BRIGHT ET AL.

Examiner

Lauren Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27,28,38-50 and 52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27,28,38-50 and 52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☒ Interview Summary (PTO-413) Paper No(s). ____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 20) ☐ Other: ____

File

DETAILED ACTION

1. Applicants amendment received via fax transmission on July 26, 2001 has been entered in the file as Paper No. 13, Amendment "D." Applicants amendment received via fax transmission on July 30, 2001 has been entered in the file as Paper No. 14, Amendment "E."
2. Claims 27, 28, 38-50, and 52 are pending.

Response to Amendment

3. In Amendment C filed as Paper No. 12, Applicant refers to an affidavit or declaration which was filed in parental application, 08/374,783. Affidavits or declarations, such as those under 37 CFR 1.131 and 37 CFR 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit or declaration, the applicant should make the remarks of record in the later application and include a copy of the original affidavit or declaration filed in the parent application. However, Examiner has reviewed the contents of said declaration and data cited therein.

CLAIM REJECTIONS - 35 USC § 112

4. Claims 26-52 were rejected under 35 U.S.C. 112, first paragraph, for not reasonably providing enablement for other plant developmental gene promoters besides the malate synthase promoter and other disrupter/inhibitor genes besides the barnase/barstar inducible promoter system that can be used to regulate a plant development phenotype. For the reasons set forth in Applicants Amendment C and after consideration of Dr. Dider Thomas' declaration (Paper No.

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7), the rejection to claims 27, 28, 38-50, and 52 under 35 U.S.C. 112, first paragraph are withdrawn.

5. Claims 26, 27, 29, 31, 33, 35, 38-40, 46, 47, 48-50, 51, and 52 were rejected under 35 U.S.C. 112, second paragraph, for being indefinite and failing to particularly pointing out and distinctly claiming the subject matter which Applicant regards as the invention. In light of Applicant cancellation of claims 51, 26, and 29-37, the rejection of said claims under 35 U.S.C. 112, second paragraph are rendered moot. In light of Applicants amendment of claims 38, 39, 40, 46, 47, and 48-50, the rejection of said claims under 35 U.S.C. 112, second paragraph is withdrawn. For the reasons of record cited below, the rejection of claims 27 and 52 under 35 U.S.C. 112, second paragraph are maintained.

Claim 27, as amended in Amendment E (Paper No. 14), recites "...plant characteristic...is essential to plant growth..." Such recitation, as noted in the previous Office Action (Paper No. 10) is indefinite because it is unclear what/which plant characteristic(s) is encompassed by the limitation of the claim; thus, the metes and bounds of the claimed invention has not been clearly defined in the recitation of said claim.

Claim 52, as amended in Amendment E (Paper No. 14), recites "A plant or seed...incapable of growing to maturity comprising a genome which includes a genetic inhibitor of seed germination or plant development...inhibitor being regulatable..." Such recitation, as noted in the previous Office Action (Paper No. 10) is indefinite because it is unclear what is encompassed by "a genetic inhibitor;" the term "genetic inhibitor" is not defined in the specification or claims and therefore, the metes and bounds of said recitation has not been

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defined. Additionally, since the term "plant development" is not defined in the specification or claims, said term also fails to define the metes and bounds of limitations encompassed in the claim.

CLAIM REJECTIONS - 35 USC § 102/103

6. Claims 26-28, 35, 42, and 47-50 were rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Bridges *et al.* (WO 90/08830). In view of Applicants cancellation of claims 26 and 35, the rejection to said claims under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a), is rendered moot. In view of Applicants amendment to claims 27, 28, 42, and 47-50, the rejection of said claims under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) is withdrawn.

New Grounds for Rejection

Priority

9. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on July 29, 1992. It is noted, however, that applicant has not filed a certified copy of the 9216151.2 application as required by 35 U.S.C. 119(b); thus, foreign priority based on said application has not been perfected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.*

10. Claims 27, 28, 39, 40, 42, 43, 45, 47, 48, 49, 50, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Oliver *et al.* (U.S. Patent No. 5,723,765).

Claims 39 and 40 are drawn to an expression system comprising: (a) an inducible promoter; (b) either a gene encoding a repressor protein under the control of said promoter or a gene encoding an inhibitor of a recombinase under the control of said disrupter; (c) a plant developmental gene promoter which can include an operator sequence recognized by said repressor protein; and (d) a gene encoding a recombinase under the control of said plant developmental gene promoter, wherein said recombinase is the FLP gene or the Cre gene. Claim 27 is drawn to said expression systems wherein the plant characteristic controlled by the system is essential to plant growth. Claim 28 is drawn to said expression systems wherein said inducible promoter is functionally linked and controls a repressor protein gene and in which the disrupter gene promoter includes an operator sequence recognized by said repressor protein. Claim 38 is drawn to said expression systems wherein said plant developmental gene promoters is selected from the group consisting of gene promoters of malate synthase, germin, glyoxysomal enzymes, aleurone layers, and carboxypeptidase. Claims 42 and 43 are drawn to said expression systems wherein said inducible promoter is the promoter of glutathione-S-transferase II or the promoter of the AlcA gene. Claim 45 is drawn to said expression systems wherein said repressor protein

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gene encodes the lac or the tet repressor. Claims 47, 48, 49, 50, and 52 are drawn to an isolated plant genome, an isolated plant, an isolated plant part, an isolated plant cell, a engineered plant or see comprising said expression systems or genome transformed via said expression systems.

Oliver *et al.* discloses a method for making genetically modified plant comprising a plant cell that has been transfected with DNA sequence comprising a first gene whose expression results in an altered plant phenotype linked to a transiently active promoter, the gene and promoter being separated by a blocking sequence flanked on either side by a specific excision sequence, a second gene that encode a recombinase specific for the specific excision sequences linked to a repressible promoter, and a third gene that encodes the repressor specific for the repressible promoter. Plant cells, tissues, seeds, and whole plants containing the above DNA sequences are also claimed (see abstract). As disclosed in claim 3 in column 35, the DNA sequences used in said method includes transiently-active promoters selected from the groups comprising a promoter active in late embryogenesis, seed development, flower development, leaf development, root development, vascular tissue development, pollen development, after wounding, during heat or cold stress, during water stress or during or after exposure to heavy metals. Also disclosed in claim 3 in column 35, the second gene of said DNA sequences used in the disclosed method are recombinases selected from a group comprising of FLP, Cre, and transposase and the corresponding specific signal sequences recognized by said recombinases. Also disclosed in claim 3 in column 35, the third gene of said DNA sequences used in the disclosed method encodes a repressor selected from the group comprising the Tn10 tet repressor and the lac operator-repressor system. In column 4, lines 5-, Oliver *et al.* defines a plant active promoter as any promoter that is active in cells of a plant of interest. In column 5, lines 48-,

Oliver *et al.* discloses that any appropriate transiently-active promoter can be used in the disclosed method and selection of an appropriate promoter will be governed by consideration such as plant type and the phenotypic trait over which control is sought.

Therefore, the invention of the above claims is anticipated by Oliver *et al.*

11. Claim 46 is rejected under 35 U.S.C. 102(e) as being anticipated by Williams *et al.* (U.S. Patent No. 5,750,867).

Claim 46 is drawn to an expression system comprising: (a) an inducible promoter; (b) a gene encoding an inhibitor of barnase under the control of said inducible promoter; (c) a plant developmental gene promoter; and (d) a gene encoding barnase under the control of said plant development gene promoter whereby the presence or absence of the exogenous chemical inducer controls whether barnase disrupts cell survival in the plant.

Williams *et al.* discloses a plant genome comprising the following DNA elements: (a) a DNA encoding a protein that inhibits or prevents the activity of said ribonuclease, wherein said protein comprises a DNA encoding barstar, under the control of a promoter which directs expression in specific plant stamen cells; (b) a gene comprising a first DNA encoding barnase under the control of a promoter that directs expression selective in microspores and/or pollen cells (see claims 1-5, 12-16, and 23-27 in columns 67-70). An example cited in column 7, lines 47- recites the barnase gene as being a "pollen-lethality" DNA sequence and the term "pollen-lethality DNA" is defined on column 6, lines 36- as encoding an RNA and/or a protein or polypeptide that ... significantly disrupts metabolism, functioning, and/or development."

Therefore, the invention of the above claims is anticipated by Williams *et al.*

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 39, 40, 41, 27, 28, 38, 42, 43, 44, 45, 47, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39, 40, and 41 recite in part (d) "...gene encoding **the** recombinase being..." A recombinase disruptor, **not a recombinase**, was previously recited in the claim; therefore, recitation of "the recombinase" lacks proper antecedent basis. In addition, claims 39, 40, and 41 recite in part (d) "...disruptor of a plant characteristic..." and "the inserted gene is a gene encoding a predetermined characteristic..." Because the term "plant characteristic" and "predetermined characteristic" has not been defined in the specification or in the claims, the metes and bounds of such recitation is unclear and renders the claim indefinite.

Claims 27, 28, 38, 42, 43, 44, 45, 47, and 52 recite "...as claimed in any of claims 39-41..." Said claims are improper because multiple dependent claims should refer to other claims in the alternative i.e. claims 39-41. See MPEP § 608.01(n).

Claim 44 recites a "...**lacc** repressor..." The recitation of "lacc" appears to be a misspelling.

Claim 45 recites "...wherein said repressor protein..." A repressor protein gene, not a repressor protein, was mentioned earlier in the recitation; therefore, the recitation of "repressor protein" lacks proper antecedent basis.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Nguyen, Ph.D. whose telephone number is 703-308-0256. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-7939 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lauren Nguyen, Ph.D.
October 1, 2001

DAVID GUZO
PRIMARY EXAMINER
David Guzo